**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**[Docket Nos. 2004D–0187, 2004D–0188, and 2004D–0189]**

# Draft Guidances for Industry on Premarketing Risk Assessment; Development and Use of Risk Minimization Action Plans; and Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of three draft guidances for industry entitled ''Premarketing Risk Assessment,'' ''Development and Use of Risk Minimization Action Plans,'' and ''Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment.'' All are dated May 2004. These draft guidances provide guidance to industry on risk management activities for drug products, including biological drug products, in the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER). The draft guidances address, respectively, premarket risk assessment; the development, implementation, and evaluation of risk minimization action plans for drug products; and good pharmacovigilance practices and pharmacoepidemiologic assessment of observational data.

**DATES:** Submit written or electronic comments on the draft guidances by [*insert date 60 days after date of publication in the* **Federal Register**]. General comments on agency guidance documents are welcome at any time.

**ADDRESSES:** Submit written requests for single copies of the draft guidances to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidances to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. Identify each set of comments with the corresponding docket number of the draft guidance as follows: Docket No. [2004D–0187] ''Premarketing Risk Assessment,'' Docket No. [2004D–0188] ''Development and Use of Risk Minimization Action Plans,'' and Docket No. [2004D–0189] ''Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment.'' See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance documents.

**FOR FURTHER INFORMATION CONTACT:** For ''Premarketing Risk Assessment'': Barbara Gould, Center for Drug Evaluation and Research (HFD–550), Food and Drug Administration, 9201 Corporate Blvd., Rockville, MD 20850, 301–827–2504, or

Patricia Rohan, Center for Biologics Evaluation and Research (HFM–485), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–3070.

For ''Development and Use of Risk Minimization Action Plans'': Christine Bechtel, Center for Drug Evaluation and Research (HFD–006), Food and Drug Administration, 1451 Rockville Pike, Rockville, MD 20852, 301–443–5572, or

Mark Weinstein, Center for Biologics Evaluation and Research (HFM–300), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–3518.

For ''Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment'': Patrick Guinn, Center for Drug Evaluation and Research (HFD–6), Food and Drug Administration, 5515 Security Lane, Rockville, MD 20852, 301–443–5590, or

Miles Braun, Center for Biologics Evaluation and Research (HFM–220), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–6090.

**SUPPLEMENTARY INFORMATION:**

## I. Background

FDA is announcing the availability of three draft guidances for industry entitled ''Premarketing Risk Assessment,'' ''Development and Use of Risk Minimization Action Plans,'' and ''Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment.'' These three guidances were produced in part to fulfill FDA's commitment to certain risk management performance goals agreed to in relation to the Prescription Drug User Fee Act upon its reauthorization in June 2002. As an initial step, FDA announced on March 7, 2003 (68 FR 11120), the availability of three concept papers. Each concept paper focused on one aspect of risk management. FDA held a public workshop on April 9–11, 2003, to obtain comment on the concept papers. The comments submitted on the concept papers and at the public meeting were considered in developing these draft guidances.

These three draft guidances address risk management issues pertinent to the successive stages of a product's lifecycle, specifically: (1) During medical

product development, (2) during product application review and approval, and (3) during the postmarketing period. The approaches recommended in the draft guidances should not be viewed as a new collection of generalized and discrete tools for risk minimization but rather as part of much broader, ongoing, and comprehensive efforts to provide additional guidance to industry on measures that can be employed to minimize the risks while preserving benefits of medical products.

The draft guidances recommend that sponsors consider specific risk minimization efforts beyond routine risk minimization measures for the few products presenting unusual types or levels of risk. In these circumstances, using strategies that go beyond routine risk assessment and minimization may further improve the product's benefit-risk balance. FDA is specifically soliciting public comment on how to best characterize the types and levels of risk that might suggest the need for a risk management plan.

FDA understands that risk management programs generate costs and place new burdens on product developers, health care practitioners, and patients. FDA recommends that, whenever possible, sponsors give every consideration to using the least burdensome method to achieve the desired public health outcome. For example, making increasing use of automatic reporting and future notification systems for adverse events will help the agency learn quickly of potential problems. Use of networks for electronic prescribing can enable the real-time, efficient collection of data on adverse events and even alert physicians to adverse events at the time of prescribing.

As new products are developed, FDA recommends that sponsors seek to identify risk signals as early as possible in a product's development cycle, to evaluate the risks, to communicate predictable risk and benefit information

effectively and thoroughly, and to employ efforts to manage these risks as efficiently as possible.

These draft guidances are being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidances, when finalized, will represent the agency's current thinking on these topics. They do not create or confer any rights for or on any person and do not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

**II. Comments**

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the draft guidances. Two copies of mailed comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket numbers found in brackets in the heading of this document. Identify each set of comments with the corresponding docket number of the draft guidance as follows: Docket No. [2004D–0187] ''Premarketing Risk Assessment,'' Docket No. [2004D–0188] ''Development and Use of Risk Minimization Action Plans,'' and Docket No. [2004D–0189] ''Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment.'' The draft guidances and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

**III. Paperwork Reduction Act of 1995**

These guidances contain information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collection(s) of information in the guidances were approved under OMB control numbers 0910–0001 (until March 31, 2005) and 0910–0338 (until August 31, 2005).

## IV. Electronic Access

Persons with access to the Internet may obtain the documents at *http://www.fda.gov/cder/guidance/index.htm*, *http://www.fda.gov/cber/guidelines.htm*, or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: April 26, 2004.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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